SYSTEM, DEVICE AND METHOD FOR PLACING A BODY IMPLANTABLE LEAD IN THE CORONARY SINUS REGION OF THE HEART

Field of the Invention

The present invention relates generally to body implantable leads such as endocardial leads for stimulating selected tissue within the heart, and more particularly, to a system, device and method for delivering and steering the distal portions of such leads into position relative to the body tissue to be stimulated and specifically the coronary sinus region of the heart.

Background of the Invention

FIG. 1 shows an example of a typical body implantable lead 10 including a lead body 12 having a distal portion 14 and a proximal portion 16. The distal portion 14 may carry a variety of combinations of pacing, sensing and/or defibrillation electrodes, all well known in the art. In the specific example shown in FIG. 1, the distal portion of the lead assembly includes a tip electrode 18 at the distal extremity of the lead body for delivering electrical stimuli to selected tissue of the heart, a sensor electrode 20 in the form of a ring electrode positioned proximally of the tip electrode 18 and a shocking or defibrillation electrode 22 disposed proximally of the sensor electrode 20. These electrodes are electrically connected to a connector assembly 24 at the proximal extremity of the lead assembly. The connector assembly 24 includes a hollow or tubular connector pin 26 and plurality of contact rings 28. Further, as is well known in the art, the connector assembly 24 may comprise a bifurcated or trifurcated structure depending upon the number and functions of the electrodes carried by the distal portion 14 of the lead assembly. A lead assembly such as that shown in FIG. 1, designed for implantation in the coronary sinus region of the heart, will typically include an anchoring or fixation means 30 including, in the example under consideration, a

sinuous configuration of the distal portion of the lead. As is known, with such a configuration the bend or bends in the distal portion of the lead press against the walls of the coronary vessel within which the distal portion of the lead is implanted and the friction caused by such biasing facilitates the anchoring or fixation of the distal portion of the lead.

Presently, the distal portions of body implantable leads such as that shown in FIG. 1 are maneuvered into position relative to the tissue to be stimulated by means of a stylet and/or a guide wire. The use of such implantation expedients is well known in the art. Thus, for example, a stylet may be passed through the hollow electrical connector pin 26 at the proximal end of the lead assembly 10 into and along a central cavity or lumen of a coiled electrical conductor or a central lumen otherwise formed in the lead body 12 to enable the implanting physician to orient the distal portion 14 of the lead assembly and to position the electrodes under fluoroscopy at a desired location within the heart. To reduce frictional resistance to advancement of the stylet within the lead body, the lumen may include a thin wall PTFE tube through which the stylet is passed. The distal extremity of the stylet typically engages a plug or other stop surface within the distal portion of the lead assembly. The stylet may comprise a steerable assembly so that a desired curvature in the distal end portion of the lead may be imparted during the introduction of the lead assembly 10 to guide it through curvatures in the patient's vascular system.

FIG. 2 is a longitudinal side view of a typical stylet 40 in use today for advancing an endocardial lead within a patient's venous system and, for left side pacing, placing the distal portion and the electrodes carried thereby within the coronary sinus region of the heart. The stylet 40 includes a main body 42 having a tapered portion 44 on the distal end of the main body and a steering knob 46 secured (usually permanently) to the proximal extremity of the main body. The knob 46 not only aids in the maneuvering and handling of the stylet but is often also used to identify the stylet. The tapered portion 44 of the main body terminates at its distal extremity in an enlarged, typically spherical tip 48 which helps prevent

perforation of the lead insulation layer and provides an enlarged area for engaging a plug or stop within the distal portion of the lead. The tapered portion 44 is relatively flexible and aids in maneuvering and steering the lead during implantation into difficult-to-reach heart regions. The main body 42 of the stylet typically comprises a relatively stiff wire of stainless steel or the like so as to facilitate the advancement of the stylet in the venous system and provide the stylet with a high degree of trackability. The main body 42, including the tapered portion 44 thereof, is typically a one piece structure. The length of the main body 42 depends on the particular implantation configuration and the length of the associated lead. Typically, a stylet is a few centimeters longer than the lead assembly that is intended to be placed thereby. By way of example, a lead assembly such as that shown in FIG. 1, having a lead body length ranging, for example, from 75 to 90cm, will be implanted using a stylet having a main body about 80 to 105cm long, that is, about 5 to 15cm longer than the associated lead body.

The implantation of a lead in the coronary sinus region is often difficult because of the extreme curvatures in the veins, their narrowness, anomalies in the vascular anatomy because of disease, and the number of veins which may communicate with the desired lead feed path. Stylets are often found to be too inflexible to be steered within the tortuous vasculature of the coronary sinus region. Thus, a more common approach to the left side implantation of an intravenous lead is the use of a flexible guide wire over which the lead is slid to its destination. For this purpose, the lead is provided with a tip electrode having a central aperture through which the guide wire can pass.

With reference to FIG. 3, there is shown a typical guide wire 50 in present use. The guide wire 50 comprises a main wire body 52 and a flexible end 54 comprising a finely coiled structure welded to the distal extremity of the main body 52. In comparison to a stylet, the guide wire 50 is relatively long, for example, 160 to 180cm in overall length or about twice as long as the lead that is to be implanted. A guide wire of such